

**ELECTRONICALLY FILED**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No. : 10/032,659 Confirmation No. 6167  
Applicant : Pamela A. Kramer et al.  
Filed : October 25, 2001  
Art Unit : 3731  
Examiner : Julian W. Woo  
Title : MANUFACTURE OF FINE-GRAINED MATERIAL FOR USE IN  
MEDICAL DEVICES  
  
Docket No.: : ACS-54306 (G2257USO1)

Customer No. : 24201 November 7, 2008

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention relates to medical devices such as for example stents, which often have extremely fine structures that are called upon to undergo deformation as well as bear substantial loads. More particularly, the invention is directed to the use of metals having a grain size in a specific range that had unexpectedly been found to be especially beneficial for medical device applications.

The present application, U.S. Serial No. 10/032,659 was filed on October 25, 2001.

## NOTICE OF APPEAL

A Notice of Appeal from the final Office action of August 13, 2008 is being filed concurrently herewith with the appropriate fees.

## ISSUE ON APPEAL

Each and every claim calls for a medical device to be formed of a metallic substrate having a grain size of between one and ten microns. None of the references cited by the Examiner suggest such range of grain size. None suggest that the claimed range of grain size would reduce cracking and/or heavy slip band formation in medical devices. The issue is whether the claimed range is obvious despite the complete absence of any teaching of what effect grain size would have on the performance of a medical device, let alone the complete absence of a teaching of ANY particular grain size.

## ARGUMENT

Independent claims 1 and 41 were rejected under 35 U.S.C. § 103(a) as obvious over Davidson (U.S. Patent No. 5,954,724) while independent claim 22 was rejected under 35 U.S.C. § 103(a) as obvious over Frantzen in view of Davidson. Both rejections rely on the Davidson reference with regard to grain size. The rejected claims specifically call for the medical device to be formed of a metallic substrate having an average grain size in the range of one to ten microns. In the thirteen columns of disclosure, there is only a single, very general mention of grain size which the Examiner relies upon as rendering the claims obvious. More specifically, at col. 8, lines 21-25, it is stated:

"In addition, the alloy can be hot or cold mechanically worked to optimize grain size, strength, elastic modulus and toughness."

Such disclosure makes absolutely no suggestion as to what effect an "optimization" of grain size could be expected to have, let alone what the optimization of grain size would entail (e.g. average size, size range, size distribution, minimum size, maximum size, etc?). Moreover, the fact that "grain size" is listed along with strength, elastic modulus and toughness as

parameters that can be optimized does not in any way suggest that the grain size would effect strength and toughness, especially in the context of a medical device.

Moreover, despite the Examiner's assertion that the reference discloses a metal alloy substrate having a "fine" grain size, applicants are unable to find any mention of a fine **grain** size. It is noted that brief mention is made at col. 9, lines 28-34 of an "omega phase" which is said to have a size of less than 25 Angstroms, i.e. about three orders of magnitude **smaller** than the range that is presently being claimed. However, while such number would at best teach away from the claimed range, it is unclear as to whether the size of a possibly minor component in a possibly transitory state would bear any relationship to the grain size of the resulting material, let alone a medical device formed therefrom.

For the rejection of claim 7, the Examiner relies on Simpson (U.S. Patent No. 4,770,725) vis-à-vis grain size. However, this reference is also silent as to any particular grain size range. Moreover, the mention of "very fine-grained two-phase microstructure" refers to a material before it is subjected to further mechanical working (col. 10, line 16, line 20, line 23 and line 24) thus precluding any conclusions to be drawn with regard to the grain size of a medical device that is ultimately formed therefrom.

For the rejection of claim 8, the Examiner relies on Braun et al (U.S. Patent No. 6,129,997) with regard to grain size. Once again, the reference relied upon, while generally referring to a "fine grained equiaxial microstructure," fails to suggest any particular grain size or grain size range. Moreover, the material is again to be subjected to further treatment (col. 2, line 7) which is said to render the material substantially coarser.

Contrary to the Examiner's assertion, the general conditions set forth in the rejected claims are not disclosed in any of the cited reference. While most any material has a multitude of physical characteristics that can be altered, there is absolutely no suggestion in any of the art cited by the Examiner that would lead one skilled in the art to believe that grain size is of any relevance with regard to cracking and/or heavy slip band formation in medical device applications. Consequently, it is the recognition of the effect of grain size on the performance of a medical device that entails the inventive step while an "optimization" of such parameter can only be undertaken AFTER such relationship has been recognized. The complete absence of any

teaching suggesting the claimed grain size range indicates that the relation had not yet been recognized, let alone the parameter optimized.

In sum, the rejections of the claims are not justifiable in view of the very general mention of grain size in the cited references and the rejections of pending claims should be withdrawn.

Respectfully submitted,

FULWIDER PATTON LLP

/Gunther O. Hanke/  
Gunther O. Hanke  
Registration No. 32,989